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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,430	10/15/2001	William S. Borneman	GC626-2D1	6652

7590 01/06/2004

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EXAMINER

PROUTY, REBECCA E

ART UNIT PAPER NUMBER

1652

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/981,430

Applicant(s)

BORNEMAN ET AL.

Examiner

Rebecca E. Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23, 25-30, 33 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33 is/are allowed.
- 6) ☒ Claim(s) 23, 25-28 and 35-39 is/are rejected.
- 7) ☒ Claim(s) 29 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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Claims 1-22, 24, 31, 32 and 34 have been canceled. Claims 23, 25-30, 33, and 35-39 are still at issue and are present for examination.

Applicants' arguments filed on 9/8/03, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 23, 25-28, and 35-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is explained in the previous Office Action.

Applicant appears to believe the amendments to the claims overcome the instant rejection. However, Claims 23, 25-28 and 35-39 remain drawn to any esterase comprising SEQ ID NO:26. SEQ ID NO:26 is a partial sequence consisting of approximately 2/3 of the esterase of SEQ ID NO:28. There is no evidence that the protein fragment of SEQ ID NO:26 has esterase activity. The only claimed common structural feature recited for the genus of esterases recited is the presence of SEQ ID NO:26. However, this shared structural feature is not correlated to the presence of

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esterase activity. As such this claimed structural feature does not constitute a substantial portion of the genus as the remainder of the structure of a polypeptide with esterase activity is completely undefined. Furthermore, the only shared functional feature of the claimed genus is esterase activity. However, this is highly diverse genus of activities as the term esterase is generic to a large number of distinct activities. Virtually all esterases known have activity on only certain types of esters. As such the claimed genus is diverse in both structural and functional features. The only species of esterase comprising SEQ ID NO:26 disclosed in the specification is SEQ ID NO:28. However, as the claimed genus is diverse in both structure and function, this single species is not representative of the entire genus.

Claims 23, 25-28, and 35-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the esterase of SEQ ID NO:28, does not reasonably provide enablement for any esterase comprising SEQ ID NO:26. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant appears to believe the amendments to the claims overcome the instant rejection. However, Claims 23, 25-28 and

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35-39 remain drawn to any esterase comprising SEQ ID NO:26. SEQ ID NO:26 is a partial sequence consisting of approximately 2/3 of the esterase of SEQ ID NO:28. There is no evidence that the protein fragment of SEQ ID NO:26 has esterase activity. As such, the breadth of the rejected claims is so enormous that the art provides insufficient guidance for enablement of the current scope. These claims encompass not only polypeptides with very minor modifications of the polypeptide of SEQ ID NO:28 but large numbers of additional polypeptides with major modifications to SEQ ID NO:28 for which the guidance in the specification and art is clearly insufficient. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. The provision of SEQ ID NO:26 fails to provide such guidance for polypeptides with major structural variations from SEQ ID NO:28 as the presence of SEQ ID NO:26 is not shown to be sufficient for esterase activity. As such polypeptides which remain encompassed within the scope of the rejected claims, the specification fails to provide enablement commensurate in scope with the claimed invention.

The rejections of the claims under 35 U.S.C. 102 and 103(a) are withdrawn in view of applicants amendments to restrict the

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claims to esterases comprising SEQ ID NO:26 or 28. de Vries et al. (1997) evidence that the esterase of Faulds et al. (1994), though highly similar to the enzyme of SEQ ID NO:28, does not comprise all of SEQ ID NO:26 or 28.

Claims 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 33 is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rebecca Prouty  
Primary Examiner  
Art Unit 1652